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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,306	03/23/2001	Wen Y. Chen	035879/0120	4654

22428 7590 01/26/2005

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/815,306

**Applicant(s)**

CHEN ET AL.

**Examiner**

Christopher H Yaen

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-57 is/are pending in the application.
- 4a) Of the above claim(s) 11-21, 23, 26 and 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-6, 22, 25, 28, 29, 33-39, 42, 45-47, 51-54 and 56 is/are allowed.
- 6) ☒ Claim(s) 7-10, 24, 30-32, 40-44, 48-50, 55 and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

**Re: Chen WY et al**  
**Priority Date: 23 March 2000**

1. The amendment filed 11/1/2004 is acknowledged and entered into the record. Accordingly, claim 2 is canceled without prejudice or disclaimer, and claims 45-57 are newly added.
2. Claims 1, and 3-57 are pending, claims 11-21,23, and 26-27 are withdrawn as being drawn to a non-elected invention. Applicant is reminded to cancel claims drawn to non-elected invention(s).
3. Claims 1,3-10,22,24-25, and 28-57 are examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

5. Claim 10 is objected to because it depends on claim 2 which is now canceled. Appropriate correction is required.

### ***Claim Rejections Maintained - 35 USC § 112,1<sup>st</sup> paragraph***

6. The rejection of claims 10,24,25,30-32,40-44, now newly added or amended claims 7-9,48-50, 55, and 57 as lacking written description under 35 USC § 112, 1<sup>st</sup> paragraph is maintained for the reasons of record. It is noted that claim 10 was inadvertently missed in the listing of claims, but was clearly discussed in the body of the rejection (i.e. claims drawn to truncated prolactin sequences). Applicant argues that the

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terms "receptor-antagonizing domain", "apoptosis-promoting domain" and positive immunomodulatory domain" are in themselves a functional characteristic of the domain. Applicant also argues that the specification provides sufficient description of such domains. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Specific and not general guidance, is required to fulfill the requirements under written description. In the instant case, one of skill in the art would not be capable of clearly distinguishing the domains claimed based solely on function alone. The description of a genus cannot be solely described by functional alone, the specification must provide some correlation between structure and function, so that one of skill in the art can adequately determine if the applicant was in possession of the claimed invention at the time of filing. The applicant then points to the specification for support of the claimed domains, however, upon closer examination of the specification, the disclosure only provides general descriptions of the domains without specifically characterizing any structure or providing representative species to be entitled to the broad genus claimed.

Applicant additionally argues that variants of the prolactin sequence are described in the specification and specifically note that the specification teaches regions of the prolactin sequence that confers its antagonistic activity. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The limitations of the specification cannot be read into the claims. As currently interpreted, the claims are drawn to any portion of a prolactin sequence, of which is not associated with a functional activity. This essentially includes an entire

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genus of fragments of which has not been adequately disclosed in the specification or adequately represented by a representative species. Since the specification fails to describe the common attributes or identifying characteristics that identify members of the genus, the disclosure of a single sequence, namely SEQ ID No: 1 is insufficient to represent the entire genus as claimed.

This rejection is now newly applied to claims 7-9,48-50,55 and 57 for the recitation of the terms positive immunomodulatory domain and growth hormone antagonist domain. Again, the specification has only provided sufficient written description of prolactin-antagonizing domains derived from SEQ ID No: 1 and therefore the written description is not commensurate in scope to claims that read on generically any and all growth hormone antagonist domains. The arguments set forth in the previous office action can be essentially applied to the genus of growth hormone antagonists now claimed.

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 11/1/2004.**

### ***Conclusion***

Claims 1,3-6,22,25,28-29,33-39,42,45-47,51-54, and 56 appear to be free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1642  
January 19, 2005

  
**GARY NICKOL**  
**PRIMARY EXAMINER**